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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/727,461 | 12/04/2003 | John D. Shaughnessy | D6485 | 6235 |

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| EXAMINER | |
|---|---|
| FETTEROLF, BRANDON J | |
| ART UNIT | PAPER NUMBER |
| 1642 | |

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/727,461 | SHAUGHNESSY, JOHN D. | |
| | Examiner | Art Unit | |
| | Brandon J. Fetterolf, PhD | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-38* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Shaughnessy, John D.
Claims Pending: 15-38

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 15, 16 in part, 17 in part, 18 in part, 19 and 20, as specifically drawn to a method of determining the risk of developing bone disease in a test individual comprising examining a soluble frizzled related protein 3, wherein the expression level is determined at the nucleic acid level, classified in class 435, subclass 6.

II. Claims 15, 16 in part, 17 in part, 18 in part, 19 and 20, as specifically drawn to a method of determining the risk of developing bone disease in a test individual comprising examining a soluble frizzled related protein 3, wherein the expression level is determined at the protein level, classified in class 435, subclass 7.1.

III. Claims 15, 16 in part, 17 in part, 18 in part, 19 and 20, as specifically drawn to a method of determining the risk of developing bone disease in a test individual comprising examining a human homologue of Dickkopf-1 (DKK1), wherein the expression level is determined at the nucleic acid level, classified in class 435, subclass 6.

IV. Claims 15, 16 in part, 17 in part, 18 in part, and 19-25, as specifically drawn to a method of determining the risk of developing bone disease in a test individual comprising examining a soluble frizzled related protein 3, wherein the expression level is determined at the protein level, classified in class 435, subclass 7.1.

V. Claims 26, 27 in part, 28 in part, 29-30, 36, 37 in part, and 38 in part, as specifically drawn to a method of treating or preventing bone disease in an individual by

habiting the expression of a soluble frizzled related protein 3, wherein the expression is inhibited at the nucleic acid level, classified in class 514, subclass 44.

VI. Claims 26, 27 in part, 28 in part, 29-30, 36, 37 in part, and 38 in part, as specifically drawn to a method of treating or preventing bone disease in an individual by habiting the expression of a soluble frizzled related protein 3, wherein the expression is inhibited at the protein level, classified in class 424, subclass 130.1.

VII. Claims 26, 27 in part, 28 in part, 29-30, 31 in part, 32 in part, 36, 37 in part, and 38 in part, as specifically drawn to a method of treating or preventing bone disease in an individual by habiting the expression of a human homolog of Dickkopf-1, wherein the expression is inhibited at the nucleic acid level, classified in 514, subclass 44.

VIII. Claims 26, 27 in part, 28 in part, 29-30, 31 in part, 32 in part, 36, 37 in part, and 38 in part, as specifically drawn to a method of treating or preventing bone disease in an individual by habiting the expression of a human homolog of Dickkopf-1, wherein the expression is inhibited at the protein level, classified in class 424, subclass 130.1.

IX. Claim 35, as specifically drawn to a kit for measuring the level of DKK1 protein in a biological sample, said kit comprises anti-Dkk1 antibodies, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method for determining the risk of developing bone disease by detecting the expression of a soluble frizzled related protein at the nucleic acid level (group I), the method for determining the risk of developing bone disease by detecting the expression of a soluble frizzled related protein at the protein level

(group II), the method for determining the risk of developing bone disease by detecting the expression of a human homolog of Dickkopf-1 at the nucleic acid level (group III), the method for determining the risk of developing bone disease by detecting the expression of a human homolog of Dickkopf-1 at the protein level (group IV), the method of treating or preventing bone disease in an individual by habiting the expression of a soluble frizzled related protein 3, wherein the expression is inhibited at the nucleic acid level (group V), the method of treating or preventing bone disease in an individual by habiting the expression of a soluble frizzled related protein 3, wherein the expression is inhibited at the protein level (group VI), the method of treating or preventing bone disease in an individual by habiting the expression of a human homolog of Dickkopf-1, wherein the expression is inhibited at the nucleic acid level (group VII), and the method of treating or preventing bone disease in an individual by habiting the expression of a human homolog of Dickkopf-1, wherein the expression is inhibited at the protein level (group VIII)are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detecting a nucleic acid or a protein and for treatment differ significantly for each of the materials. For detecting the nucleic acid, a hybridization assay may be used. For detecting a protein, an immunoassay utilizing an antibody may be used. For treating a disease, any route of administration may be used using either an inhibitor at the nucleic acid level or at the protein level. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-VIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VIII.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
4/29/08